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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,873	11/01/2002	Anand Ranganathan	SHW-009US	4622
959 7590 10/15/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/009,873	<b>Applicant(s)</b> RANGANATHAN, ANAND	
	<b>Examiner</b> Frank W. Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-692)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### ***CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on July 30, 2007 have been entered. The claims pending in this application are claims 1 and 3-21 wherein claims 18-20 have been withdrawn due to species election. Rejection and /or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on July 30, 2007.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3-17, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is rejected as vague and indefinite in view of the phrase "said 3' recognition sequence being combined with a DNA methylation recognition sequence" in step a) of the claim because it is unclear that this phrase means that said 3' recognition sequence is adjacent to a DNA methylation recognition sequence or said 3' recognition sequence comprises a DNA methylation recognition sequence or mean something else? Please clarify.

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5. Claim 1 is rejected as vague and indefinite in view of steps b) to d). Since step b) does not indicate that an accessible restriction site in a starting DNA construct is identical to the restriction enzyme site of said restriction enzyme, it is unclear how to cleave the ligated product containing a DNA modification generated in step c) with said restriction enzyme in step d).

Please clarify.

6. Claim 1 recites the limitation “the same restriction enzyme” in step a) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “restriction enzyme” before “the same restriction enzyme”. Please clarify.

7. Claim 1 recites the limitation “the cleaved DNA construct” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “cleaved DNA construct” in steps a) and b). Please clarify.

8. Claim 1 is rejected as vague and indefinite in view of step d) because it is unclear that said 5' restriction enzyme recognition sequence of said first desired DNA unit is from the ligated product containing a DNA modification generated in step c) or not. Please clarify.

9. Claim 1 is rejected as vague and indefinite because there are two different steps e) in the claim. In view of the whole claim, it appears that the first step e) should be deleted. Please clarify.

10. Claim 1 is rejected as vague and indefinite in view of step f) because it is unclear that said 5' restriction enzyme recognition sequence of said first desired DNA unit is from the next ligated product containing a DNA modification generated in step c) or not. Please clarify.

11. Claim 1 is rejected as vague and indefinite in view of steps e) to g). Since the cleaved next ligated product produced from step f) in step g) is different from the cleaved ligated product

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from step d), it is unclear how to perform step g) by repeating steps e) and f) using the cleaved ligated product from step d). Please clarify.

12. Claim 4 recites the limitation “the cleaved DNA construct from step b)” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “cleaved DNA construct” in step b). Please clarify.

13. Claim 4 is rejected as vague and indefinite because it is unclear whether an accessible Xba I site in step d) is identical to an accessible Xba I site in step b) or not. If an accessible Xba I site in step d) is identical to an accessible Xba I site in step b), “an accessible Xba I site” in step d) should be “the accessible Xba I site”. Please clarify.

14. Claim 4 is rejected as vague and indefinite in view of steps e) to g). Since the cleaved next ligated product produced from step f) in step g) is different from the cleaved ligated product from step d), it is unclear how to perform step g) by repeating steps e) and f) using the cleaved ligated product from step d). Please clarify.

15. Claim 5 recites the limitation “the restriction enzyme recognition sequences” in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase “restriction enzyme recognition sequences” in claim 4. Please clarify.

16. Claim 8 is rejected as vague and indefinite because it is unclear that the ligated product in the claim means the ligated product from steps c) and d) or the next ligated product from steps e) and f). Please clarify.

17. Claim 9 is rejected as vague and indefinite in view of steps e) to g). Since the next cleaved product produced from step f) in step g) is different from the next cleaved product from

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step e), it is unclear how to perform step g) by repeating step f) using the cleaved ligated product from step d). Please clarify.

18. Claim 10 is rejected as vague and indefinite in view of steps d) to f). Since the cleaved product produced from step e) in step f) is different from the cleaved product produced from step c) in step e), it is unclear how to perform step f) by repeating steps d) and e) using the cleaved product produced from step c) in step e). Please clarify.

19. Claim 13 is rejected as vague and indefinite because there is no phrase "a subsequent desired DNA unit" in step c) of claim 9 or 10.

### ***Conclusion***

20. No claim is allowed.

21. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

October 9, 2007

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

FRANK LU  
PRIMARY EXAMINER